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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,652	05/30/2006	Joanne Chory	532792000800	9156

20872 7590 10/28/2008

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,652	CHORY ET AL.	
	Examiner	Art Unit	
	STUART F. BAUM	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *14-22,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 23-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/13/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence search results (2)*.

DETAILED ACTION

1. Claims 1-38 are pending.

2. Applicant's election with traverse of Group I, claims 1-13 and 23-36 in the reply filed on 7/23/2008 is acknowledged. The traversal is on the ground(s) that the presently amended claims define a special technical feature that is novel over the prior art (Page 8, 4th paragraph).

This is not found persuasive because Applicants have amended claim 1 to recite "wherein said PFT1 protein is encoded by a nucleotide sequence hybridizing to SEQ ID NO:2 under *stringent* wash conditions…". The Office contends the recitation "stringent" is not defined and therefore the Office interprets said recitation to mean low stringency conditions (see below). Therefore, Halliday teaches the recited technical feature and the restriction is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14-22 and 37-38 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claims 1-13 and 23-36, including SEQ ID NO:2 encoding SEQ ID NO:3 are examined in the present office action.

Specification

4. Objection is made to the specification for not incorporating SEQ ID NO's when referring to nucleic acid or amino acid sequences. 37 CFR 1.821(d) requires the use of the assigned sequence identifier (e.g. SEQ I.D. NO: X) in all instances where the description or claims of a patent application discuss sequences. For example, sequence identifiers are missing from Figure 9.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth herein. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Information Disclosure Statement

5. Only the titles listed in the International Search Report have been considered. The recitation "International Search Report" is not appropriate for printing on the front of a patent.

Claim Objection

6. Claim 27 is objected to for reciting "sequence hybridizing" instead of --sequence that hybridizes".

Claim 1, line 2 is objected to for not writing out PHYTOCHROME AND FLOWERING TIME1 in capital letters.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-5, 7-8, 10-13, 23-24, 27, 29-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for reciting "stringent". Applicants have not set forth the metes and bounds of "stringent wash conditions". All subsequent recitations of "stringent" are also rejected.

Scope of Enablement

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-13, 23-24 and 27-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant nucleic acid sequence comprising SEQ ID NO:2 or comprising a nucleotide sequence encoding SEQ ID NO:3, and expression vector comprising said recombinant nucleic acid operably linked to a promoter and transgenic plant comprising said vector wherein the plant has an early flowering phenotype compared to a wild-type plant and a method for decreasing flowering time in a plant comprising transforming a plant with said vector, does not reasonably provide enablement for any nucleic acid sequence exhibiting less than 100% sequence identity to SEQ ID NO:2 or any nucleic acid sequence encoding a protein exhibiting less than 100% sequence identity to SEQ ID NO:3 and plant transformation therewith or any method comprising said nucleic acid sequence or any method of modulating at least one photosensitive trait in a plant comprising said nucleic acid sequence or wherein said sequence encodes SEQ ID NO:3 or wherein said sequence comprises SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method of modulating at least one photosensitive trait in a plant comprising altering the level of PHYTOCHROME AND FLOWERING TIME 1 (PFT1) protein in a plant, wherein said PFT1 protein is encoded by a nucleotide sequence hybridizing to SEQ ID NO:2 under stringent wash conditions or has an amino acid sequence at least 45% identical to SEQ ID NO:3, wherein the photosensitive trait is any one of the traits listed in claim 2, or wherein said PFT1 protein comprises a conservative variant of SEQ ID NO:3, or wherein the nucleotide sequence encodes a conservative variant of SEQ ID NO:3, or wherein the nucleotide sequence comprises SEQ ID NO:2, or a transgenic plant having at least one modulated photosensitive trait comprising a recombinant expression vector that expresses said nucleotide sequence; or a recombinant nucleic acid sequence that hybridizes to SEQ ID NO:2 under stringent wash conditions or encodes a protein that has at least 45% identity to SEQ ID NO:3.

Because of the 112 2nd rejection of "stringent" as discussed above, the Office interprets "stringent wash conditions" to mean low stringency wash conditions.

Applicants disclose the Arabidopsis PFT1 cDNA sequence as SEQ ID NO:2 and the predicted amino acid sequence as SEQ ID NO:3 (page 30, paragraph 123; and sequence listing). Applicants disclose that PFT1 Is a single copy gene with 15 exons (page 32, paragraph 128). Applicants state "The predicted protein has 836 amino acids, a predicted vWFA (von Willebrand factor type A) domain in the N-terminus and a Gln rich region in the carboxy-terminus, reminiscent of some transcriptional activators (Fig. 5a). vWFA domains are widely distributed among all phyla (Ponting, et al. *J Mol Biol* 289, 729-45 (1999)). They are involved in various cellular processes and a high proportion have a divalent cation binding site that in some cases has been shown to mediate protein-protein interactions (Hinshelwood, et al. *J Mol Biol* 298, 135-47 (2000)). The DxSxS motif involved in coordination with a divalent cation is converted to ExSxA in *PFT1*. It is unclear whether this partially conserved motif can still bind a metal." (page 32, paragraph 128). Applicants disclose overexpression of PFT1 caused an early flowering phenotype, suggesting that PFT is limiting for flowering (page 33, top paragraph).

The Office contends Applicants' claims are drawn in part to methods, plants and nucleic acids that hybridize to SEQ ID NO:2 or encode a protein exhibiting less than 100% identity to SEQ ID NO:3 or conservative variants of SEQ ID NO:3. Applicants have not included a functional limitation that distinguishes those sequences with the desired function from those sequences that do not encompass the desired function. Without a recognized correlation between structure and function, those of ordinary skill in the art would not be able to identify without further testing which of those nucleic acids that hybridize to SEQ ID NO:2 or encode a protein

having at least 45% sequence identity to SEQ ID NO:3 or encode conservative variants of SEQ ID NO:3 would also have the same function as the protein of SEQ ID NO:3.

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that hybridize to SEQ ID NO:2 under stringent conditions will encode a protein with the same activity as a protein encoded by SEQ ID NO:2. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences. Therefore, the instant specification fails to provide guidance for which amino acids of the protein encoded by SEQ ID NO:2 can be altered, the type of alteration, and which amino acids must not be changed, to maintain activity of the encoded protein. The specification also fails to provide guidance for

which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein.

Applicants claims are drawn to nucleic acid sequences that hybridize to SEQ ID NO:2, but the state-of-the-art teaches isolating DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al (1999, Plant Molecular Biology 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65^0C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2).

Re: claim 1 recites altering the level of PFT1 in a plant which encompasses a multitude of methods, only one of which Applicants have disclosed. Altering the level of expression can be accomplished by for example, by chemical means, physical means or through genetic manipulations, e.g., transgenes. Applicants have only disclosed transforming a plant with a nucleic acid which encodes a protein. Applicants are not enabled for any of the other multitude of ways to alter the level of a PFT1 protein.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences,

either by using non-disclosed fragments of SEQ ID NO:2 as probes or by designing primers to undisclosed regions of SEQ ID NO:3 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce a plant with an earlier flowering time compared to a wild-type plant.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al (2001, NCBI Accession Number AC079281).

The claims are drawn to a recombinant nucleic acid sequence comprising SEQ ID NO:2, or comprising a nucleotide sequence encoding SEQ ID NO:3, or that hybridizes to SEQ ID NO:2 under stringent wash conditions or comprises a nucleotide sequence encoding a protein at least 45% identical to SEQ ID NO:3.

Lin et al disclose a nucleic acid sequence that exhibits 67% sequence similarity to Applicants' SEQ ID NO:2 (sequence search results included) and wherein the sequence of Lin et al encodes a protein that exhibits 83% identity with Applicants' SEQ ID NO:3 (sequence search results included). The Office contends the sequence of Lin et al is in fact the gene encoding Applicants' PFT1 protein because the sequence is from Arabidopsis, as is Applicants' sequence,

comprises 15 exons, as is disclosed in the sequence search result for DNA encoding SEQ ID NO:3 and because Applicants state the PFT1 gene is a single copy gene. The Office contends the differences in the sequence are due to sequencing errors. The Office contends that the sequence of Lin et al would hybridize to Applicants' SEQ ID NO:2. The sequence of Lin et al is a recombinant sequence and as such, Lin et al anticipate the claimed invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claim 34 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 34 is drawn to a seed of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three quarters of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed progeny (seeds), it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy , Coats, and Malik* 195 USPQ 344, (CCPA) 1977. The amendment of the claims to recite that the seeds comprise the construct that was introduced into the parent would overcome the rejection.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
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Art Unit 1638
October 23, 2008